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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,358	03/04/2002	David Tumey	VAC.702.US	3855
7590	07/06/2004		EXAMINER	
Kinetic Concepts, Inc. Attn: Nadeem Bridi P.O. Box 659508 San Antonio, TX 78265-9508			TRUONG, LINH T	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 07/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/090,358	TUMEY, DAVID	
	Examiner Linh Truong	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

#### A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on \_\_\_\_.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-10 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>4/5/04</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-10 (according to the newly renumbered claims) have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Objections***

Claim 4 is objected to because of the following informalities: the word "senor" should be changed to "sensor". Appropriate correction is required.

### ***Claim Rejections -35 USC ~ 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henley et al. (Henley) '6,458,109 in view of Hibner et al. (Hibner) '6,120,462.

For claims 1 and 5, Henley teaches a wound treatment apparatus with a bandage assembly that includes a drainage bandage 20 (screen means) that contacts the wound and a delivery bandage 18 that seals the drainage bandage 20 and the wound site (col. 5, lines 11-17), a vacuum source fluidically communicating with the drainage bandage

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20 via flexible tube 24, a sensing device (172 or 174) and a collection canister (164 or 166). Henley does not expressly teach that the sensing device is placed between the screen means and the vacuum source nor does he expressly teach that the collection canister is placed between the screen means and the sensing device. Pressure sensors are commonly known in the art for sensing if there is too little vacuum pressure or too much vacuum pressure. Hibner teaches a fluid collection system with a main vacuum line 328 that attaches canister 318 to a vacuum pump 330 with a pressure sensor 328 interposed between the canister 318 and the vacuum pump 330 (fig. 14 and col. 15, lines 51-63). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the invention of Henley with the same line connections of the canister, sensor, and vacuum source of Hibner for sensing pressure more accurately.

The Applicant also states that the sensor can be placed at other positions and does not specifically state why the placement of the canister is important [0026]. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place the sensing device between the screen means and the vacuum and to place the canister between the screen means and the sensing device, since it has been held that rearranging of parts of an invention involves only routine skill in the art. *In re Japikse* , 86 USPQ 70.

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Claims 2-3, 6 and 10, are rejected under 35 U.S.C. 103(a) as being unpatentable over Henley et al. (Henley) '6,458,109 in view Hibner et al. (Hibner) '6,120,462 and in further view of Overton et al. '5,611,846.

For claims 2-3, 6 and 10, in addition to the 103 rejection above, Henley does not teach that the sensing device comprises a gas chromatograph comprising of a photo diode. Gas chromatographs are commonly used in the art to identify the contents of gaseous samples. Overton et al. teaches a portable gas chromatograph comprising a photoionization (which contains a photo diode) detector (col. 12, lines 23-26). Therefore it is obvious to one with ordinary skill in the art at the time the invention was made to substitute the sensor of Hibner for the gas chromatograph of Overton et al. in order to detect microorganisms/infection in the drainage fluids.

Claims 4, 6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henley et al. (Henley) '6,458,109 in view Hibner et al. (Hibner) '6,120,462 and in further view of Lewis et al. '6,017,440.

For claims 4, 6 and 10, in addition to the first 103 rejection above, Henley does not teach that the sensing device comprises a sensor array. Lewis et al. teach sensor arrays for detecting microorganisms/infection. Therefore it is obvious to one with ordinary skill in the art at the time the invention was made to substitute the sensor of Hibner for the sensor array of Lewis et al. in order to detect microorganisms/infection in the drainage fluids.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henley et al. (Henley) '6,458,109 in view of Hibner et al. (Hibner) '6,120,462 and in view of

Scherson et al. '5,855,570 and in further view of Lewis et al. '6,017,440.

For claim 7, Henley does not disclose a dressing (screen means) that is embedded with a sensing device for detecting infections. Scherson et al. teaches an oxygen- producing bandage with several layers, wherein one of the layers comprise a sensor (col. 4, lines 31-39). Lewis et al. teach sensor arrays for detecting microorganisms/infection. Therefore it is obvious to one with ordinary skill in the art at the time the invention was made to provide the invention of Henley with a dressing embedded with a sensor in order to detect the infections at the wound area.

NOTE: In response to Applicant's argument that Henley teach (and now Hibner) teaches away from an oxygen-rich environment, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henley et al. (Henley) '6,458,109 in view of Hibner et al. (Hibner) '6,120,462 in view of Fleischmann '6,398,767 and in further view of Lewis et al. '6,017,440.

For claim 8, Henley does not teach that the sensing device senses infections and is disposed on the sealing means. Fleischmann teaches a wound treatment apparatus that comprises a sealing means 14 and a sensing device 38 that is disposed on the sealing means 14 and is in contact with a screen means 12 (fig.1 and col. 4, lines 62-

64). Lewis et al. teach sensor arrays for detecting microorganisms/infection. Therefore, it is obvious to one with ordinary skill in the art at the time the invention was made to provide the sealing means of Henley with a sensing device to detect infections in the atmosphere near the wound area.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henley et al. (Henley) '6,458,109 in view of Hibner et al. (Hibner) '6,120,462 in view of Parker et al. '4,955,391 and in further view of Lewis et al. '6,017,440.

For claim 9, Henley discloses a canister and a sensing device outside of the canister but does not disclose a sensing device for sensing infections located in the canister. It is well known in the art that canisters are used as collection devices for fluids, and, thus, the fluids can be assessed. Parker et al. teaches a fluid monitoring apparatus comprising a canister 22 with a sensing probe 64 mounted inside the canister (col.5, lines 16-21). Lewis et al. teach sensor arrays for detecting microorganisms/infection. Therefore, it is obvious to one with ordinary skill in the art at the time the invention was made to substitute the sensing probe of Parker et al. with the sensing array of Lewis and to modify the location of the sensing device from being placed outside of the canister to being placed within the canister (as taught by Parker) for more accurate sensing of infections within the canister.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Linh Truong whose telephone number is 703-605-4974. The examiner can normally be reached on Mondays through Fridays from 8:30am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Calvert can be reached on 703-305-1025. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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